of this section or withdraw the proposal if comments opposing the amendment are persuasive. A new drug application may be submitted in lieu of, or in addition to, a petition under this paragraph.

(ii) A new drug application may be submitted in lieu of a petition to amend the OTC drug monograh only if the drug product with the condition that is the subject of the new drug application has not been marketed on an interim basis (such as under the provisions of paragraph (a)(6)(iii) of this section), all clinical testing has been conducted pursuant to a new drug application plan, and no marketing of the product with the condition for which approval is sought is undertaken prior to approval of the new drug application. The Food and Drug Administration shall handle a new drug application as a petition for amendment of a monograph, and shall review it on that basis, if the provisions of this paragraph preclude approval of a new drug application but permit the granting of such a petition.

(b) *Regulatory action.* Any product which fails to conform to an applicable monograph after its effective date is liable to regulatory action.

(c) Information and data submitted under this section shall include, with respect to each nonclinical laboratory study contained in the application, either a statement that the study was conducted in compliance with the good laboratory practice regulations set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(d) [Reserved]

(e) *Institutional review and informed consent.* Information and data submitted under this section after July 27, 1981, shall include statements regarding each clinical investigation involving human subjects, from which the information and data are derived, that it either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter, or was not subject to such requirements in accordance with §§ 56.104 or 56.105, and that it was conducted in compliance with the requirements for informed consent set forth in part 50 of this chapter.

(f) *Financial certification or disclosure statement.* Any clinical data submitted under this section must be accompanied by financial certifications or disclosure statements or both as required by part 54 of this chapter.

[39 FR 11741, Mar. 29, 1974, as amended at 39 FR 39556, Nov. 8, 1974; 42 FR 19141, Apr. 12, 1977; 42 FR 54800, Oct. 11, 1977; 46 FR 8460, 8955, Jan. 27, 1981; 46 FR 14340, Feb. 27, 1981; 46 FR 21360, Apr. 10, 1981; 46 FR 47738, Sept. 29, 1981; 50 FR 7516, Feb. 22, 1985; 55 FR 11581, Mar. 29, 1990; 63 FR 5253, Feb. 2, 1998]

§ 330.11 NDA deviations from applicable monograph.

A new drug application requesting approval of an OTC drug deviating in any respect from a monograph that has become final shall be in the form required by § 314.50 of this chapter, but shall include a statement that the product meets all conditions of the applicable monograph except for the deviation for which approval is requested and may omit all information except that pertinent to the deviation.

[39 FR 11741, Mar. 29, 1974, as amended at 55 FR 11581, Mar. 29, 1990]

§ 330.12 Status of over-the-counter (OTC) drugs previously reviewed under the Drug Efficacy Study (DESI).

(a) There were 420 OTC drugs reviewed in the Drug Efficacy Study (a review of drugs introduced to the market through new drug procedures between 1938 and 1962). A careful review has been made of the reports on these drugs to determine those drugs for which implementation may be deferred without significant risk to the public health, pending review by appropriate OTC drug advisory review panels and promulgation of a monograph.

(b) On and after April 20, 1972, a number of notices were published in the FEDERAL REGISTER concerning previously unpublished OTC drugs reviewed by the National Academy of Sciences-National Research Council Drug Efficacy Study Group. Only the evaluations and comments of the panels were published, with no conclusions of the Commissioner of Food and Drugs. Those publications were for the